STORAGE NAME: h0431z.hcl ****FINAL ACTION****
DATE: May 13, 1999 ****SEE FINAL ACTION STATUS SECTION****

HOUSE OF REPRESENTATIVES
AS REVISED BY THE COMMITTEE ON
HEALTH CARE LICENSING & REGULATION
FINAL ANALYSIS

BILL #: HB 431 **(Passed as SB 1396)**

RELATING TO: Drugs, Devices and Cosmetics

SPONSOR(S): Representative Lynn

COMPANION BILL(S): SB 1396(s), SB 2468(c), and HB 951(c)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH CARE LICENSING & REGULATION YEAS 10 NAYS 0
(2) BUSINESS REGULATION AND CONSUMER AFFAIRS YEAS 8 NAYS 0
(3) HEALTH & HUMAN SERVICES APPROPRIATIONS (W/D)
(4)
(5)

I. FINAL ACTION STATUS:

SB 1396 was substituted for HB 431 and passed on April 21, 1999. HB 431 was laid on the table. SB 1396 was approved by the Governor on May 13, 1999. It was codified into chapter 99-165, Laws of Florida.

II. SUMMARY:

HB 431 exempts certain medical devices from being registered, and exempts their manufacturing companies from having to pay a $20 biennial product registration fee to the Department of Health (department). Manufacturers of Class II and Class III devices are exempted from registering and paying the fees. Most of the administrative aspects of registration for Class II and Class III devices will remain in effect since a device manufacturer must submit documentation (pre-market notification letter or pre-market approval number) for the medical devices manufactured in Florida when applying for a permit.

Currently, medical device manufacturers must register medical devices manufactured in Florida with the department. The two-year registration fee is required for each separate and distinct product. Variations in physical characteristics such as size, package, shape, or color, or instances of the same medical device being marketed under different brand names, are considered identical products and do not require payment of the registration fee.

The department estimates that approximately 2,750 separate and distinct medical devices are registered with the department annually. Thus, on an annual basis, the Drug, Devices and Cosmetics Trust Fund will not collect annual fees of an estimated $27,500. There will be no fiscal impact on local government and the private sector in general.

III. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Currently, section 510 of the federal Food, Drug and Cosmetic Act requires United States device manufacturers and distributors to annually register their establishments and to file a list of their devices with the United States Food and Drug Administration. Section 201(h) of the federal Food, Drug and Cosmetic Act defines medical devices. Medical devices are subject to general controls and other controls of the federal Food, Drug and Cosmetic Act. General controls are baseline requirements that apply to all medical device manufacturers. Medical devices, unless otherwise exempt, must be properly labeled, and packaged, be approved for marketing by the FDA, meet their labeling claims, and be manufactured under good manufacturing practices, which is a mandated quality assurance system. The United States Food and Drug Administration has established classifications for approximately 1,700 different generic types of devices and has grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are: Class I (General Controls); Class II (General Controls and Special Controls); and Class III (General Controls and Pre-Market Approval). Most Class I devices are subject to general controls such as requirements for the manufacturer to annually register with and to file a list of their devices with the FDA, and design and manufacture devices under good manufacturing practices.

In addition to general controls, Class II and Class III devices are subject to further requirements including special controls and premarket approval by the FDA. Class II devices include any device for which reasonable assurance of safety and effectiveness can be obtained by the imposition of special labeling requirements, mandatory performance standards, patient registries and postmarket surveillance. Class III devices include devices that may support or sustain human life, are important in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Class III devices require premarket approval by the FDA to be marketed. A premarket notification is a marketing application submitted to the FDA to demonstrate that the medical device to be marketed is as safe and as effective or substantially equivalent to a legally marketed device that was or is currently on the United States market and that does not require premarket approval. Class III devices must be submitted for premarket approval by the FDA to evaluate the safety and effectiveness of the devices.

Florida duplicates the federal requirements. Chapter 499, Florida Statutes, provides for the regulation of drugs, cosmetics and household products by the Department of Health. Medical device manufacturers must register and list the medical devices manufactured in Florida with the Department of Health. Florida does not have any approval authority over medical devices, they can only register the manufacturer and list the items manufactured in Florida. The registration classes include Class I, Class II, and Class III medical devices as defined by the federal law.

The registration class is determined by the level of control required to operate or use the device. Class I devices are the simplest and Class III the more complex items. For instance, Class I items are devices such as, walking canes and Band-AIDS. Class II devices require a pre-market notification letter and includes items such as, blood pressure cuffs and gas machines for anesthetics. Class III devices require a pre-market submission letter and includes items such as, pacemakers and heart valves.

The two-year registration fee is $20 per separate and distinct product. Variations in physical characteristics such as size, package, shape, or color and the same medical device marketed under different brand names are considered identical products and do not require payment of the registration fee.

A Certificate of Free Sale, a document required by many foreign countries before a product can enter their country, attests to the marketable status of the product in Florida. The department has statutory authority to issue a certificate on any product that is required to be registered (and is so registered) under the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes.

As part of its review to improve access to investment capital, the Health Technology Industry Advisory Council to Enterprise Florida, Inc., recommended a reduction or elimination of Florida's medical device registration and fee for any device manufactured or assembled in Florida that has been approved by the FDA.

B. EFFECT OF PROPOSED CHANGES:

Manufacturers of Class I devices are exempted from paying the fees, but are required to register their products.

Manufacturers of Class II and Class III devices are exempted from registering and paying the fees. Most of the administrative aspects of registration for Class II and Class III devices will remain in effect since a device manufacturer must submit documentation (pre-market notification letter or pre-market approval number) for the medical devices manufactured in Florida when applying for a permit. Also, by exempting registration of these two classes of devices, the manufacturer will not be eligible to receive a Certificate of Free Sale from the department. However, a similar certificate is available from the federal government, which serves the same purpose as the Florida Certificate of Free Sale.

The department estimates that approximately 2,750 separate and distinct medical devices currently registered with the department annually will no longer be required to be registered.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

N/A

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

N/A

(3) any entitlement to a government service or benefit?

N/A

b. If an agency or program is eliminated or reduced:

(1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

(2) what is the cost of such responsibility at the new level/agency?

N/A

(3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

a. Does the bill increase anyone's taxes?

No.

b. Does the bill require or authorize an increase in any fees?

No.

c. Does the bill reduce total taxes, both rates and revenues?

No.

d. Does the bill reduce total fees, both rates and revenues?

Yes. An estimated 2,750 devices will not be registered annually. The estimated reduction in annual fees to the Drug, Devices and Cosmetics Trust Fund is $27,500.

e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

N/A

b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

N/A

4. Individual Freedom:

a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

N/A

b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

N/A

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

N/A

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. STATUTE(S) AFFECTED:

Section 499.015, Florida Statutes

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 499.015, Florida Statutes, by adding subsection (8), to exempt manufacturers of Class II and Class III medical devices from registration and paying the registration fee. However, the medical device manufacturer must submit evidence of registration, listing, and approval by the United States Food and Drug Administration at the time it submits its application for a permit to do business in Florida. It defines the evidence for Class II and Class III medical devices or components of devices. It exempts manufacturers that are required to register devices under s. 499.015, from the annual product fee provided in s. 499.041(6), Florida Statutes, if they meet certain conditions.

Section 2. Provides an effective date of July 1, 1999.

IV. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

None.

2. Recurring Effects:

See Fiscal Comments.

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

None.

2. Direct Private Sector Benefits:

Certain medical device manufacturers in Florida will avoid paying approximately $27,000 annually in fees payable to the state under the Florida Drug and Cosmetic Act, ch. 499, Florida Statutes.

3. Effects on Competition, Private Enterprise and Employment Markets:

There will be no effect on private enterprise and employment markets. However, exporters of Class II and Class III medical devices manufactured in Florida, will no longer be able to obtain a Certificate of Free Sale from the State of Florida. While they may obtain a certificate from the federal government, it involves a much longer processing period. This could impact their ability to compete internationally.

D. FISCAL COMMENTS:

The department estimates that approximately 2,750 separate and distinct medical devices currently registered with department annually will no longer be required to be registered. The registration fee per device is $20 for two years, or $10 per year. Thus, on an annual basis, the Drug, Devices and Cosmetics Trust Fund will not collect annual fees of an estimated $27,500 (2,750 @$10 each).

V. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

VI. COMMENTS:

This bill deletes the requirement for certain medical device manufacturers to pay the product registration fee. As reported by the department:, "other manufacturers in Florida, ie., prescription drug, over-the-counter drug, compressed medical gas, and cosmetic manufacturers, are still required to register and pay the biennial registration fee for their products. They might decide that they shouldn't have to pay to register their products, if medical device manufacturers don't have to pay the registration fee." According to the department, the bill provides that a manufacturer submit evidence of registration, listing, and approval at the time the manufacturer submits an application to the department for a permit to do business in Florida as required by s. 499.013(2)(d), F.S.

The bill is not clear as to whether the manufacturer is required to continue to submit to the department such evidence for new products or changes to previously reported products during the two year permit renewal period. According to the department, a manufacturer should report evidence for new products and any changes to previously reported products at the time they submit a renewal application for a permit. However, the language in the bill exempts the manufacturer from all of s. 499.015, F.S., except the requirement to obtain a permit to do business in Florida. This would appear to make it difficult for the department to enforce submission of evidence of new products or changes to previously reported products.

VII. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

A strike everything amendment was adopted and the bill as amended was passed by the Committee on Health Care Licensing and Regulation at its March 18, 1999 meeting. The amendment was mostly clarifying and conformed the bill to the basic language of SB 1396. Also, the amendment clarified that a manufacturer has to provide updated information when they submit a renewal application for a permit.

VIII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:	Staff Director:
Robert W. Coggins	Lucretia Shaw Collins

AS REVISED BY THE COMMITTEE ON BUSINESS REGULATION AND CONSUMER AFFAIRS:

Prepared by:	Staff Director:
Gip Arthur	Rebecca R. Everhart

FINAL ANALYSIS PREPARED BY THE COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:	Staff Director:
Robert W. Coggins	Lucretia Shaw Collins